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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:			
Joseph R. BYRUM		Art Unit:	1631
Appln. No.:	09/421,106	Examiner:	Y. Kim
Filed:	October 15, 1999	Atty. Docket:	16517.142
For:	Nucleic Acid Molecules and Other Molecules Associated with Plants		

#15

APPELLANT'S BRIEF

Commissioner for Patents
Washington, DC 20231

Sir:

This is an Appeal from the Final Rejection of all claims pending in the above-described patent application. A Notice of Appeal was filed on November 29, 2001. The statutory fee of $320.00 for submitting this Brief is included in our attached Check No. 200896. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167. Monsanto Company is a subsidiary of Pharmacia Corporation, located at 100 Route 206 North, Peapack, New Jersey 07977.

2. Related Appeals and Interferences

The Appellant is unaware of any Appeals or Interferences related to this Appeal.[1]

[1] Appellant is aware that the U.S. Patent and Trademark Office has rejected co-pending application no. 09/552,087 (filed April 21, 2000) under the judicially created doctrine of obviousness-type double patenting as being

3. Status of Claims

Claims 1-9 and 16-18 are pending. Claims 17 and 18 were withdrawn from consideration by the Examiner, and are not under appeal. Claims 1-9 and 16 stand finally rejected under 35 U.S.C. §§ 101 and 112, first paragraph, and claims 1 and 4 stand finally rejected under 35 U.S.C. § 102. Appellant appeals all of the rejections of claims 1-9 and 16.

4. Status of Amendments

Applicant has not filed any responses subsequent to the Final Office Action mailed August 29, 2001 in this case.

5. Summary of Invention

The invention is directed to nucleic acid molecules that are capable of specifically hybridizing to a second nucleic acid molecule. In particular, the present invention is directed to nucleic acid molecules that are capable of specifically hybridizing to a second nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 10 and complements thereof. The invention is also directed to vectors comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 10.

6. Issues

The issues in this Appeal are:

(a) whether claims 1-9 and 16 are unpatentable under 35 U.S.C. § 101 for allegedly being unsupported by a specific asserted utility or a well established utility;

(b) whether claims 1-9 and 16 are unpatentable under 35 U.S.C. § 112, first paragraph for alleged lack of enablement because the claimed invention purportedly lacks utility;

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unpatentable over claims 1-9 and 16 of the present application. *See* Office Action mailed September 19, 2001 (Paper No. 7) in application no. 09/552,087.

(c) whether claims 1-9 and 16 are unpatentable under 35 U.S.C. § 112, first paragraph for alleged insufficiency of written description; and

(d) whether claims 1 and 4 are unpatentable under 35 U.S.C. § 102 for alleged anticipation.

7. Grouping of Claims

Patentability of claims 1-9 and 16 is addressed together in Sections 8.A through 8.D below. Separate patentability of claims 1 and 4 is addressed in Section 8.E below. A copy of the claims on appeal is attached hereto as Appendix A.

8. Argument

A. Summary of Appellant's Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility....where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicant has met his part of the bargain – he has disclosed nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example use to identify the presence or absence of a polymorphism. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed nucleic acids provide at least this benefit, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed nucleic acids for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

Furthermore, Applicant have provided an adequate description of the claimed nucleic acids that demonstrates Applicant's possession of the claimed invention. Each genus of claimed nucleic acid molecules, *i.e.*, the nucleic acid molecules comprising the nucleic acid sequences of

SEQ ID NOs: 1 through 10 and their complements, has been described by the recitation of a common structural feature – the nucleotide sequences of SEQ ID NOs: 1 through 10, and their complements, respectively – which distinguishes molecules in the genus from molecules not in the claimed genus. Because the specification demonstrates that Applicant has possession of (and has provided an adequate description of) the claimed genus of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112.

Claims 1 and 4 were erroneously rejected as anticipated by two references which fail to teach any of the recited nucleic acid sequences. The Examiner improperly considered non-identical chemical compounds to anticipate claim 4 as drawn to SEQ ID NOs: 2 and 8, despite the fact that the references fail to teach the chemical compositions of SEQ ID NOs: 2 and 8. Moreover, the Examiner based his rejections for anticipation of claim 1 not on what exists in the art or what the art teaches. Instead, the rejections of claim 1 are based on the Examiner's theory, unsupported by any evidence, that the prior art sequences might hybridize to the recited nucleic acids under the recited hybridization conditions. Such clearly unsupported conjecture is simply not a proper basis for an anticipation rejection.

B. The Claimed Nucleic Acids Have Legal Utility

Pending claims 1-9 and 16 were erroneously rejected under 35 U.S.C. § 101 because the claimed inventions were allegedly not supported by either a "substantial utility" or a "specific asserted utility." Final Action mailed August 29, 2001 (Paper No. 15) ("Final Action") at pages 2-5. According to the Final Action, the asserted utilities are "neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds." Final Action at page 5.

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson*. The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of

providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

Applicant has asserted in the specification that the claimed nucleic acid molecules provide identifiable benefits, for example use to identify the presence or absence of a polymorphism, and use as a hybridization probe for expression profiling. *See, e.g.*, specification at page 47 line 17 through page 54, line 16, and page 54, lines 17-26. Either of these utilities alone is enough to satisfy Section 101. Because Applicant need only establish a single utility to satisfy 35 U.S.C. § 101, and he has done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

(1) The Claimed Nucleic Acid Molecules Provide A Specific Benefit, *i.e.*, They Have Specific Utility

Applicant has asserted that the claimed nucleic acid molecules[2] are themselves useful for utilities disclosed in the specification, *e.g.*, to detect the presence or absence of polymorphisms, and as hybridization probes for expression profiling. The specification also discloses additional utilities for the claimed nucleic acid molecules, including introduction of the claimed nucleic acid molecules into a plant or plant cell (either as sense or antisense inhibitors), which can then be used to screen for compounds such as a herbicide. Specification at page 77, line 8 through page 78, line 11. For example, a compound can be provided to both an antisense plant and a control plant (no antisense) and the effect of the compound on the plant can be monitored. Such a screen is analogous to a cell-based assay, which has a legally sufficient utility.[3] Thus, the use in such a screen of a plant or plant cell having an introduced claimed nucleic acid molecule is a legally sufficient utility. Other utilities disclosed in the specification include use of the claimed nucleic acid molecules to measure the level of mRNA in a sample,[4] and use as molecular markers.[5]

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[2] It is irrelevant whether the corresponding mRNA or polypeptide have utility because Applicant is not relying on utility of the mRNA or polypeptide to establish utility of the claimed nucleic acid molecules.

[3] *See, e.g.*, MPEP § 2107 at page 2100-25.

[4] It is standard practice to screen populations of nucleic acids with EST sequences, often attached to a microarray, without characterizing each and every target mRNA. Knowing that the gene corresponding to the claimed nucleic acid molecules is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect expression changes in traits of interest, *e.g.*, drought stress. Contrary to the Examiner's assertions, this use is not using the claimed nucleic acid molecules to identify a "'real world' context of use." *See* Final Action at page 5. It is a **use** of the claimed nucleic acid molecules in a real world context.

[5] One can use the claimed nucleic acid molecules to determine location of a corresponding DNA sequence on a physical map or genetic map location without knowing anything beyond the claimed sequence. The use of molecular markers is a practical activity in the development of nutritionally enhanced or agriculturally enhanced crops. Such markers are useful in, for example, genetic mapping or linkage analysis, marker-assisted breeding, physical genome mapping, transgenic crop production, crop monitoring diagnostics, and gene identification and isolation. As more markers are identified, genetic maps will become more detailed and it will be easier for plant breeders to breed for particular traits.

(a) Identifying the Presence or Absence of a Polymorphism

One of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 47, line 17 through page 54, line 16. The Examiner argues that this utility, like all of the asserted utilities, is not specific or substantial, *see* Final Action at page 5, but does not provide any support (legal or factual) for the proposition that detection of polymorphisms is not a legal utility.

Many of the disclosed utilities in this case, including this utility, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The Examiner denigrates this utility by asserting that these uses are not "useful" because a scientist would not know how to use the information gathered or the nucleic acid molecule being measured. *See* Final Action at pages 5-6. However, the fact that, for example, a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107 at page 2100-25.

Use of the claimed nucleic acid molecules to detect the presence or absence of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the gas.[6] Likewise, the claimed nucleic acid molecules

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[6] For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit – to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

(b) Probes for Other Molecules or Source for Primers

Other uses for the claimed nucleic acid molecules are as probes for other molecules or as a source of primers. The Examiner suggests that these uses are not legal utilities because the "result of [] hybridization, however, does not produce any real world application useful to one of ordinary skill in the art." Office Action mailed March 14, 2001 (Paper No. 10) at page 4. This is not correct. The specification discloses that the claimed nucleic acid molecules can be used, via hybridization, in real world applications such as to isolate nucleic acid molecules of other plants and organisms such as *Glycine max*, alfalfa, *Arabidopsis*, barley, *Brassica*, broccoli, cabbage, etc.[7] Specification at page 30, line 20 through page 31 line 6. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and so has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

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[7] Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Applicant to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules.

One illustrative example of a molecule that can be isolated using the claimed nucleic acid molecules is the promoter of the gene corresponding to the claimed nucleic acid molecules. Applicant has specifically disclosed that one use of the claimed nucleic acid molecules is to initiate a chromosome walk. Specification at page 42, line 1 through page 44, line 19. The Final Action denigrates that utility when it asserts that it is a utility that is applicable to nucleic acids in general. Final Action at pages 4-5.

In short, the Final Action appears to be arguing that the utility is not a legal utility simply because other molecules can be used for the same purpose, *i.e.*, chromosome walks. That position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Moreover, it is factually incorrect that this use is not "specific" to the claimed nucleic acids. The claimed nucleic acid molecules provide a particularly appropriate and demonstrably useful starting point for a walk to isolate a promoter that is active in *Glycine max*. A random nucleic acid molecule does not provide an equally good starting point to isolate such a promoter. Furthermore, even if a random nucleic acid molecule provided a <u>better</u> starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed nucleic acid molecules. An invention may be "less effective than existing devices but nevertheless meet the

statutory criteria for patentability." *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

The Examiner has failed to provide evidence, or even to suggest a reason for believing that the claimed nucleic acid molecules could not be so used. Accordingly, the assertion of this utility as a probe for other molecules or as a source of primers satisfies the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

(2) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility

It appears that the Final Action is arguing that the disclosed uses are legally insufficient or "insubstantial" under 35 U.S.C. § 101, but such an argument has no basis in law. The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). "'Practical utility' is a shorthand way of attributing 'real world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use").[8]

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, for example to detect the presence or absence of polymorphisms. The detection of polymorphisms provides an immediate benefit to the public because, for example, it enables a plant breeder to determine the distribution of parental genetic material in the progeny of a cross. This information about a

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[8] *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (C.C.P.A. 1974).

plant's genetic profile, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

Quite apart from the detection of polymorphisms, there is also no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed "real world" value to such nucleic acid molecules. The utility of ESTs is not merely an academic issue; the real world value of ESTs is self-evident from the growth of a multi-million dollar industry in the United States premised on the usefulness of ESTs. Like fermentation processes involving bacteria, ESTs and nucleic acid molecules with EST sequences are "industrial product[s] used in an industrial process – a useful or technical art if there ever was one." *See, e.g., In re Bergy*, 563 F.2d 1031, 1038, 195 U.S.P.Q. 344, 350 (C.C.P.A. 1977).

The market participants for EST products are primarily sophisticated corporations and highly knowledgeable scientists who are unlikely to pay for useless inventions. *Compare Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983) ("People rarely, if ever, appropriate useless inventions"). Quite simply, the commercial value of ESTs is proof of their real world value and of the benefits they provide to the public. This evidence cannot be ignored. The patent system was created to serve and foster growth and development in the industrial arts. If the industries themselves recognize and appreciate the value of an invention, it is not for the Patent Office to say that they are mistaken.

(3) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 706.03(a)(1). Cases in which utility was found not to be credible are rare, and usually involve "hare-brained" utilities.[9]

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[9] Examples of incredible utilities are given in MPEP § 2107 at page 2100-26, and include:

> an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v.*

A challenge to the credibility of a utility is essentially a challenge directed to operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 706.03(a)(1).

Applicant has explicitly identified specific and substantial utilities, not only in the specification, but in Applicant's Response dated December 12, 2000 at page 5, lines 13 through 24. "To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no evidence that the claimed nucleic acid molecules will not work for the disclosed utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

C. The Claimed Nucleic Acids Are Enabled by the Specification

The enablement of the claimed nucleic acid molecules has been challenged. Claim 1 was erroneously rejected as not enabled by the specification, because the claimed nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Final Action at page 6. This rejection has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of

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Quigg, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

D. The Specification Provides An Adequate Written Description of the Claimed Invention

Despite the Examiner's admission that SEQ ID NOs: 1-10 are adequately described by the specification, the adequacy of the written description of the claimed invention has been challenged by the Examiner because the nucleic acid molecules of all of the claims are allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s)...had possession of the claimed invention." Final Action at page 6. The bases for the Examiner's challenge are that (1) one of skill in the art would allegedly conclude that Applicant was not in possession of the claimed nucleic acid molecules, and (2) there is allegedly an "insufficient written description to support the genus encompassed by the claim." Final Action at pages 6-7. These are not proper bases for a written description rejection of a "comprising" claim. If they were, every "comprising" claim ever written would be invalid for failing to describe every nuance of the claimed invention. Furthermore, the specification demonstrates to one skilled in the art that Applicant was in possession of the claimed genera of nucleic acid molecules.

(1) The Specification Reflects Applicant's Possession of the Claimed Invention

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art, *e.g.*, a molecular biologist, would, after reading the present specification, understand that Applicant had possession of SEQ ID NOs: 1-10 and their complements, and therefore, the claimed invention.

Applicant has provided the nucleotide sequences required by the claims, *e.g.*, SEQ ID NOs: 1-10, vectors comprising these nucleotide sequences, and bacterial artificial chromosomes comprising these nucleotide sequences, and has thus established possession of the claimed invention. The fact that the claims at issue are intended to cover molecules that include the recited sequences joined with additional sequences, or that hybridize under specific conditions to the recited sequences does not mean that Applicant was any less in possession of the claimed nucleic acid molecules.[10] It is well-established that use of the transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156

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[10] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then it goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

The present application describes more than just the nucleotide sequence required by the claims (SEQ ID NOs: 1 through 10), for example, it describes vectors comprising the claimed nucleic acid molecules (specification at page 12, line 8 through page 13, line 25, and page 59, line 7 through page 67, line 5). Furthermore, the addition of extra nucleotides or detectable labels to the disclosed nucleotide sequences (SEQ ID NOs: 1 through 10) is readily envisioned by one of ordinary skill in the art upon reading the present specification,[11] in particular at page 13, lines 15-19 (describing sequences with labels to facilitate detection), page 34, line 9-17 (describing fusion nucleic acid molecules), and page 12 line 25 through page 16, line 8 (citing references describing the construction, manipulation and isolation of nucleic acid macromolecules).

(2) Applicant Has Described the Claimed Invention

The Examiner asserts that because Applicant has not disclosed "sequences from other species, mutated sequences, allelic variants, splice variants, [and] sequences that have a recited degree of identity", Applicant has allegedly not adequately disclosed the claimed genus. Final Action at page 6. The Examiner appears to assert that each nucleic acid molecule within the claimed genus must be described by its complete structure. Final Action at page 7. These assertions are totally unfounded. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the*

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[11] It is established patent jurisprudence that Applicant need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicant has satisfied that test for written description.

In particular, Applicant has disclosed common structural features, for example the nucleotide sequences of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, etc. For example, if a particular vector contains the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of vectors comprising a nucleic acid sequence of SEQ ID NO: 1. *See* claim 8. Moreover, closely related nucleic acid molecules falling within the scope of claim 1 and its dependents are readily identifiable - they either hybridize under the claimed conditions to SEQ ID NOs: 1-10 (or complements thereof) or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification. Thus, claims 1-9 and 16 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed.

E. The Claimed Nucleic Acid Molecules Are Novel

The Examiner has challenged the novelty of the claimed nucleic acid molecules in the Final Action. Claims 1 and 4 were erroneously rejected under 35 U.S.C. § 102(b), for allegedly being anticipated by Laten *et al.* (hereinafter "Laten") and Larkins *et al.* (hereinafter "Larkins") (Examiner's Sequence Homology Search). Final Action at page 9.[12]

Laten and Larkins do not anticipate the present claims. For a prior art reference to anticipate in terms of 35 U.S.C. §102, every element of the claimed invention must be identically

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[12] The Final Action appears to base the anticipation rejection solely on the Laten reference, but at one point mentions the Larkins reference. Final Action at page 9. Because the rejection over Larkins was withdrawn in the Office Action mailed March 14, 2001 (Paper No. 9) on page 6, the mention of Larkins in the Final Action is assumed to be a typographical error. However, in the interest of facilitating prosecution, and without conceding that the claimed invention has actually been rejected twice under Larkins, Applicant herein submits argument directed to this reference.

shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 U.S.P.Q. 2d 1315, 1317 (Fed. Cir. 1988). *See also Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). Neither Laten nor Larkins teach every element of the claimed invention.

(1) The Art of Record Fails to Anticipate Claim 4

Although Laten is cited for the proposition that it anticipates claim 4 as directed to SEQ ID NO: 8, and Larkins is cited for the proposition that it anticipates claim 4 as directed to SEQ ID NO: 2, the Examiner admits that Laten and Larkins do **not** disclose the sequence of SEQ ID NO: 8 or SEQ ID NO: 2, respectively. Final Action at page 9. In fact, the sequence of Laten is asserted only to "exhibit 94.2% local similarity match to that of SEQ ID Number 8" and the sequence of Larkins is asserted only to have "63.6% local similarity match to the claimed SEQ ID No 2." Final Action at page 9. Because the chemicals disclosed in Laten and Larkins are not the same as the chemicals disclosed as SEQ ID NO: 8 or SEQ ID NO: 2, every element of the claimed invention has not been identically shown in this reference. *See Diversitech Corp.*, 850 F.2d at 677, 7 U.S.P.Q.2d at 1317. Accordingly, neither Laten nor Larkins anticipate claim 4.

(2) The Art of Record Also Fails to Anticipate Claim 1

The Examiner contends that Laten and Larkins anticipate claim 1, and asserts:

> Larkins et al. disclose a nucleic acid sequence...capable of hybridizing to the fragment of the claimed SEQ ID number. As for the limitations of claim 1, drawn to a specific hybridization conditions, the USPTO does not have a facility to conduct experimental procedures according to the set forth hybridization/wash conditions and therefore, it is assumed that the nucleic acid sequence of Laten et al. would hybridize under said conditions.

Final Action at page 9. This assertion is incorrect.

The Laten sequence has only 58.3% identity to SEQ ID NO: 8. The Examiner has not established or provided a basis for the assertion that the small region of homology cited by the Examiner (308 basepairs having 94.2% identity) is sufficient to permit hybridization of the entire Laten sequence (4190 total basepairs having only 58.3% identity). Likewise, the Larkins sequence has only 8.5% identity to SEQ ID NO: 2. The Examiner has not established or provided a basis for the assertion that the small region of homology cited by the Examiner (76 basepairs having 63.6% identity) is sufficient to permit hybridization of the entire Larkins sequence (897 total basepairs having only 8.5% identity). No evidence, extrinsic or otherwise, has been presented by the Examiner in support of the proposition that the Laten or Larkin sequences are capable of hybridizing to any of the recited SEQ ID NOs under the recited conditions.

In conclusion, neither Laten nor Larkins expressly or inherently anticipate claim 4 because neither reference teaches SEQ ID NO: 2, SEQ ID NO: 8, or any of the other claimed nucleic acid molecules. Further, neither reference anticipates claim 1 because no evidence has been provided in support of the Examiner's proposition that the Laten and Larkins sequences will hybridize to the recited nucleic acids under the recited hybridization conditions. As such, claims 1 and 4 of the present invention are not expressly or inherently anticipated by Laten or Larkins, and the rejections must be withdrawn.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

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APPENDIX A

1. A substantially purified nucleic acid molecule, said nucleic acid molecule capable of specifically hybridizing, under conditions of 6.0 x sodium chloride/sodium citrate (SSC) at about 45°C, followed by a wash of 2.0 x SSC at 50°C, to a second nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 10 and complements thereof.

2. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule comprises a microsatellite sequence.

3. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule comprises a region having a single nucleotide polymorphism.

4. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule comprises a nucleic acid molecule having a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 10 and complements thereof.

5. The substantially purified nucleic acid molecule according to claim 4, wherein said nucleic acid molecule further comprises a bacterial ORI site.

6. The substantially purified nucleic acid molecule according to claim 1, wherein said nucleic acid molecule has a promoter or partial promoter region.

7. The substantially purified nucleic acid molecule according to claim 6, wherein said promoter region comprises a CAAT cis element and a TATA cis element and an additional cis element.

8. A vector comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 10.

9. The vector according to claim 8, wherein said vector further comprises a second nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 10, wherein said second nucleic acid sequence is not identical to the first nucleic acid sequence.

16. The vector of 8, wherein said vector is a bacterial artificial chromosome.